Remarks

Claims 1, 4, 5, 7, 9-11 and 28 were previously pending in the subject application. By this amendment, the applicants have canceled claims 4 and 7, amended claims 1 and 5, and added new claim 29. No new subject matter has been added by this amendment. Accordingly, claims 1, 5, 9-11, 28 and 19 are now before the Examiner for her consideration. The amendments and claim cancellations set forth herein should not be interpreted to indicate that the applicants have agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 4 and 7 have been rejected under 35 U.S.C. §112. By this amendment, claims 4 and 7 have been cancelled, thus rendering these rejections moot.

Claims 1, 4, 7 and 9-11 have been rejected under 35 U.S.C. §112, first paragraph. The applicants respectfully traverse this grounds for rejection because the claims currently presented for examination are fully enabled by the application as filed.

The applicants have unexpectedly discovered a process which, for the first time, makes it possible to efficiently grow *Pasteuria* endospores *in vitro*. This is a very important contribution to the art because *Pasteuria* are known to be effective biological control agents for nematodes. Crop losses due to phytopathogenic nematodes are in the billions of dollars each year. Efforts to control nematodes with chemicals, such as methyl bromide, take a heavy toll on the environment. Alternatives to chemical control strategies have been desperately needed for years.

Although *Pasteuria* was first reported as far back as 1888, all attempts to culture the microbe *in vitro* have failed to produce a viable means of producing endospores. Without the ability to grow *Pasteuria in vitro* it is not possible to produce enough *Pasteuria* to effectively address the massive nematode problem. Therefore, there remains in this art a great and longstanding need for a method of producing *Pasteuria* by spore formation following true *in vitro* growth of the vegetative phase of *Pasteuria* on an artificial growth medium. Such systems were not known until the subject invention.

The applicants' ability to produce *Pasteuria in vitro* has enormous implications for the development of this technology for the replacement of toxic nematacides such as methyl bromide.

Like many pioneering inventions the applicants' discovery of their simple, but unique, process was largely the result of serendipity. Standard methodology in this field calls for the sterilization of culture media. The current applicants discovered, quite by chance, that sterilization of the media kills the very microbes which make *in vitro* culture techniques possible for *Pasteuria.*

The applicants initially isolated and identified one particular microbe that can be used to support *Pasteuria* growth. Although the applicants initial efforts focused on the first microbe isolated with their unique protocol, it is readily apparent that the applicants' discovery opens the door for readily identifying and utilizing other microbes that support *in vitro Pasteuria* growth. In this regard, one aspect of the current invention is the recognition that microbes useful for supporting *in vitro Pasteuria* growth are found in association with nematodes. In the subject application the applicants also have provided a specific nucleotide sequence which can also be used to identify microbes useful according to the subject invention. Armed with this information, as well as the other detailed information provided in the subject application, the skilled artisan can readily, and without undue experimentation, identify other microbes that can be used to promote *in vitro Pasteuria* growth.

The outstanding Office Action focuses on the applicants' previous recitation in claim 1 of a nucleotide sequence to which certain microorganisms useful according to the subject invention have hybridizing DNA. Please note that the hybridization characteristic was by no means the only criteria recited in claim 1. However, to expedite prosecution, the applicants have removed this recitation from claim 1. Of particular note for the practice of the subject invention is the recitation in claim 1 that the microorganisms used according to the subject invention are found in association with nematodes. This recitation substantially limits the scope of the applicants' claims and provides critical guidance to those skilled in the art as they practice the subject invention.

The applicants respectfully submit that a careful analysis of the Wands factors leads to the conclusion that the applicants' claims, as currently pending, are fully enabled.

The first Wands Factor to be considered is the quantity of experimentation needed. In the current case only a modest amount of routine experimentation is needed to practice the invention as now claimed. Microbes, which have evolved to be associated with nematodes, can be obtained from

nematodes using well known procedures including those described at page 9 of the specification. Furthermore, if DNA hybridization is to be used, the DNA of the microbes can be easily tested to determine whether it hybridizes to SEQ ID NO. 1. Hybridization assays are well known to those skilled in the art and are described in extensive detail at pages 12-17 of the subject application. For microbes associated with nematodes, which have DNA that hybridizes with SEQ ID NO. 1, the skilled artisan can then follow the procedures outlined extensively in the specification to determine if the microbe supports *Pasteuria* growth. This is all very straightforward — no creativity or judgment whatsoever is required. These procedures could be readily conducted in a week or two by a high school student.

As the examiner noted in the outstanding Office Action, the requirement for some experimentation and/or screening does not necessarily make a claim non-enabled. "Enablement is not precluded by the necessity for some experimentation such as routine screening. . . A considerable amount of experimentation is permissible, if it is merely routine . . ." (emphasis added). *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). In the current case, any experimentation needed to identify other microbes would be routine given the guidance provided in the subject application. This guidance includes the identification of the microbes as being associated with nematodes as well as providing a specific DNA sequence.

The next Wands factor is the amount of direction or guidance provided by the applicants. The application, as filed, provides a detailed description of every step needed to practice the invention. There is no need for any innovation.

Wands Factor Number Three pertains to the presence or absence of working examples. The subject application gives a detailed description of each step of the process and provides an example of a positive result. The applicants have subsequently obtained additional positive results using the procedures described in the subject application.

With regard to Wands Factor Number Four, the nature of the invention is unquestionably very simple. It is entirely unexpected, yet simple and easy to perform.

Although the prior art did not each the applicants' unique solution to a longstanding problem, the prior art does teach each and every step needed to practice the invention. In fact, these

procedures are extremely easy to practice. Thus, Wands Factor Number Five also supports a conclusion that the applicants' claims are enabled.

With regard to Wands Factor Number Six, although those working in this field are, in fact, highly skilled, they would not need to be in order to practice this invention. There is nothing complicated or difficult about the practice of the current invention.

With regard to the predictability of this art, now that applicants have supplied a solution to this long standing problem, the ability to practice the invention in accordance with the applicants' teachings is very predictable. The ability to identify additional microbes that are useful in the practice of the subject invention is particularly enhanced by the knowledge, provided by the current applicants, that of particular interest are microbes associated with nematodes that have DNA that hybridizes with SEQ ID NO. 1.

Finally, with regard to the breadth of the claims (Wands Factor Number Eight), the applicants respectfully submit that the claims now before the examiner are quite narrowly defined and are consistent in scope with other claims that have issued for microbiological inventions. Furthermore, the scope of the claims is perfectly reasonable for an invention such as this that opens the door through which others may so easily pass.

The applicants respectfully submit that, to limit their patent coverage to the one specific deposited strain of bacteria, would essentially eviscerate their patent protection. Others skilled in the art, with minimal effort, could readily identify other microbes associated with nematodes which could be used to support *in vitro* growth of *Pasteuria*.

The Federal Circuit's predecessor, the Court of Customs and Patent Appeals (CCPA), has directly addressed the issue of claim scope for pioneer inventions. In addressing the enablement of relatively broad claims based on a limited disclosure the CCPA noted:

> On remand, appellants may be found to have been in fact the first to conceive and reduce to practice "a solid polymer" as set forth in claim 13. As pioneers, if such they be, they would deserve broad claims to the broad concept. What were once referred to as "basic inventions" have led to "basic patents," which amounted to real incentives, not only to invention and its disclosure, but to its prompt, early disclosure. . . .Appellants disclosed, as the only then existing way to make such a polymer, a method of making the crystalline form. ... To restrict appellants to the

> crystalline form disclosed, under such circumstances, would be a poor way to stimulate invention, and particularly to encourage its early disclosure. To demand such restriction is merely to state a policy against broad protection for pioneer inventions, a policy both shortsighted and unsound from the standpoint of promoting progress in the useful arts, the constitutional purpose of the patent laws. See *In re Goffe, 542 F.2d 564, 191 USPQ 429 (CCPA 1976)*. (emphasis added).

It is well settled in the Patent Law that pioneer inventions are entitled to a scope of protection which is commensurate with the contribution made to the art. Here, the current applicants have made an enormous contribution by making it possible, for the first time, to efficiently and easily grow a biocontrol agent which is urgently needed to help replace toxic chemicals that pollute our environment.

The claims as now presented clearly delineate the scope of the claimed subject matter as that which is taught in detail in the applicants' specification. Specifically, the characteristics of particular microbes which facilitate *in vitro Pasteuria* growth are recited. The subject application gives ample disclosure regarding the use of these microbes in the applicants' *in vitro* system. Thus, a person skilled in the art could readily make and use the invention, as claimed, without undue experimentation. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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DRS/la
Attachment: Petition and Fee for Extension of Time; and
Marked-up Version of amended claims

Marked-up Version of Amended Claim

Claim 1 (twice amended):

A method for producing *Pasteuria* endospores *in vitro*, said method comprising introducing *Pasteuria* into a growth medium, wherein said growth medium comprises a microorganism or a chemical compound produced by a microorganism, wherein said microorganism is found in association with nematode[s and has DNA which hybridizes with SEQ ID NO. 1 under moderate to high stringency conditions]; wherein said method comprises growing the *Pasteuria* in said growth medium, and obtaining said endospores.

Claim 5 (amended):

The method, according to claim 1, wherein said microorganism has all the identifying characteristics of ATCC PTA-2324.